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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,760

12/21/2006

Patrick Deluca

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

09/13/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,760	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1613	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                    |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                                | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/19/2005</u> . | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

1. The examiner acknowledges receipt of response to restriction requirement filed 7/01/2010, IDS filed 9/19/2005. Claims 1-15 are pending.

***Priority***

2. The examiner acknowledges this application as a 371 of PCT/US04/08399 filed 3/19/2004, and which claims benefit of US provisional application 60/455,590 filed 3/19/2003.

***Election/Restrictions***

3. Applicant's election without traverse of Group I, claims 1 and 2 (claim 2 is linking) in the reply filed on 7/01/2010 is acknowledged. Therefore claims 3-15 are withdrawn from consideration.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Woo et al. ("Preparation Na Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for protein Delivery," in Pharmaceutical Research, Vo. 18, No. 11, November, 2001).
6. Woo teaches a composite microsphere comprising PLGA, poly(Acryloyl Hydroxyethyl Starch) (AcHES) and proteins such as bovine serum albumin and horseradish peroxidase (see the whole document). The molecular weight of bovine serum albumin is known at 66,382 Da and

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that for Horseradish peroxidase is known at 40,000 Da and these molecular weights anticipate the molecular weight range of 200 to about 160,000 Da.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. ("Preparation and Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for protein Delivery," in Pharmaceutical Research, Vol. 18, No. 11, November, 2001) in view of Filvaroff et al. (US 20020058614).

10. Woo has been described above to anticipate claim 1. Woo teaches that the composite microsphere comprising PLGA and poly(Acryloyl Hydroxyethyl Starch) (ACHES) for delivery of proteins such as bovine serum albumin and Horseradish (66,832 Da for BSA and 40,000 Da

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for Horseradish). Woo does not use the composite microsphere with the peptide claimed in claim 2.

11. However, it is known that PLGA microspheres have been used as carriers from insulin (see para. [0199], [0414], [0430], [0438], [0439] and [0451]).

12. Therefore, since PLGA microspheres are known for carrying insulin, one having ordinary skill in the art at the time the invention was made would have expected that the composite microsphere of Woo comprising PLGA and polyacryloyl hydroxyethyl starch would be effective in carrying and delivering insulin because PLGA has been effective for the delivery of insulin.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1613